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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,889	01/18/2002	Emil A. Tanagho	02307E-080710US	3329

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EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/052,889

Applicant(s)

TANAGHO ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 5, 2005 has been entered.

***Election/Restrictions***

Applicant elected Group III, claim 24 for prosecution. Because of the amendment filed along with the election, no claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention because the only remaining claims are drawn to the elected invention. Election was made **without** traverse in Paper No. 5 filed December 11, 2003.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 24-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 8, and 10 of U.S. Patent No. 6,371,992. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are so similar that they are considered obvious over each other. This is due to the fact that the bladder (patented claims) and the ureter or urethra as presently claim, are from the same tract and connected to each other. For this reason, it would have been obvious to make a matrix from one or the other because of their similarity in structure and function.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bishopric et al (US 5,855,620) or Goldstein (US 5,632,778) or Abraham et al (US 5,993,844) in view of Gregory (US 5,990,379). Bishopric (see column 3, lines 45-68) or Goldstein (see column 3, lines 11-20 and column 5, line 10 to column 6, line 52) or Abraham (see column 3, line 53 to column 5, line 51) all disclose producing intact collagen and elastin matrixes but not of ureter or urethra tissue as claimed. However, Gregory teaches that it was known to make intact elastin matrixes out of ureters; see column 4, lines 16-39 and column 5,

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lines 36-55. Therefore, it is the Examiner's position that it would have been obvious to make ureter tissue matrixes in the Bishopric or Goldstein or Abraham so that the particular tissue could be replaced in a recipient who needs such.

Regarding claims 26-28, the claimed properties would inherently be present because the primary references as modified by Gregory produce the same material as that claimed.

### ***Response to Arguments***

With regard to the double patenting rejection, Applicants have decided to withhold filing a terminal disclaimer until the claims are otherwise allowable. For this reason, the rejection has been maintained.

Applicants also tried to use a 37 CFR 1.131 declaration to overcome the Section 103 Abraham rejection, but this was considered insufficient. In particular, using the Probst publication as evidence of earlier invention goes against a court decision on the matter in *In re Costello*; see MPEP 716.10, the paragraph immediately preceding the examples (this section is incorporated herein by reference). In addition, the claimed invention is not disclosed by the Probst article in that it does not fall within the claimed scope; see MPEP 715.02, which is incorporated herein by reference. For this additional reason, the declaration is considered insufficient.

In addition, Applicants attempt to argue that Probst is an actual reduction to practice of the claimed invention. In response, the Examiner notes that Probst does not disclosed the claimed invention or a species that falls within the claim scope. Furthermore, actual reduction requires that the Applicants constructed

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the claimed invention and that it operated for its intended purpose; see MPEP 2138.05 that is incorporated herein by reference. Since at least the first prong of the two prong test is not met, the declaration cannot be accepted as adequate.

Furthermore, the Applicants argue that the claimed invention and that of Probst are similar enough to be obvious, yet Applicants also argue that the primary references, of the Section 103 rejection, are not similar enough to be obvious. This appears to be inconsistent.

Applicants argue that "matrix" means a cross-linked interwoven mesh-like structure. However, this definition is not consistent with the accepted meaning of the term in the art, which is broader in scope. Rather, "matrix" means a mixture of materials or structures upon which cells can grow.

Next, Applicants traverse the combination of Bisphoric and Goldstein with Gregory because they are not drawn to the same tissues as the secondary reference of Gregory. This is considered unpersuasive because of the fact that Bisphoric, Goldstein, and Gregory all disclose treatment of vascular tissues. This provides the nexus between the primary and secondary references and suggests that there would be no unreasonable expectation of success as argued.

Furthermore, the argument that Gregory uses a method that removes collagen is considered unpersuasive because one cannot show unobviousness by arguing references individually; see MPEP 2145 (IV), which is incorporated herein by reference.

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### ***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic  
Primary Examiner  
Art Unit 3738